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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,200	BREDDAM ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *15-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The 2nd Claim 39 has been renumbered as---claim 49---, as per rule 37 CFR 1.126.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 01/24/07 and the supplemental response of 1/30/07 have been entered. Claim 1 has been amended. Claims 1-49 are pending.

Applicant reiterates that claim 1 is a linking claim for the products of claims 15-41 and 45-47. However, Examiner maintains that while the barley plant/part thereof of claim 1 is used to prepare the malt/wart composition and beverage of claims 15-41, the different products have different structures and function. Therefore, claim 1 is neither a linking claim for claims 15-41, nor that the claims are eligible for rejoinder.

MPEP 821.04 states, " where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. Claims 42-44 are drawn to methods for preparing the barley plant of claim 1 and claims 45-47 are drawn to methods for producing beverage and malt/wart compositions using the barley plant of claim 1. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1-14 and 48-49 are examined.

Claims 15-47 are withdrawn from consideration as being directed to the non-elected invention.

Claim Objections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 are confusing in the recitation of "wherein the embryos of said plant comprise less than 5% of the LOX-1 activity of the embryos of a wild-type barley" when

the barley plant of claim 1 (in which the claims are depending from) has a total loss of LOX-1 function. Since the barley plant of claim 1 has null LOX-activity, it is unclear how the embryos of the plant can still comprise LOX-1 activity. Clarification is required to more clearly define the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutgersson et al (Enzymes (1997), Vol. 74 (6), pp. 727-732) in view of Kleinhofs et al (Mutations Research (1978) 51:29-35). This rejection is repeated in part for the reasons of record as set forth in the last Office action of 10/24/06. Applicant's arguments filed 01/24/07 and 1/30/07 have been fully considered but are not deemed persuasive.

The claims are drawn to a barley plant or a part thereof, having mutation in the LOX-1 gene that resulted total loss of LOX-1 function; wherein the embryos of said plant comprises less than 5% of the LOX-1 activity of the embryos of a wild-type barley plant; wherein said plant/plant part comprises less than 1% LOX protein of a wild-type barley plant; said barley plant or part thereof produced by the method steps as listed in the claim 5. The claims are also drawn to said barley plant or part thereof, wherein the gene encoding LOX-1 contains a premature nonsense codon or splice site mutation.

Rutgersson et al teach a process to inactivate lipoxygenase in barley cultivar Blenheim. Rutgersson et al teach that low lipoxygenase activity in barley is desirable because it improves oxidative stability of cereal product, and that lipoxygenase is the main factor in off-flavor production in malt. Table II shows remaining activity of lipoxygenase was 2% (for experiment 13).

While Rutgersson et al do not explicitly teach a barley plant with null LOX1 activity or less than 1% of LOX as compared to a wild-type, Rutgersson et al do indicate that total inactivation of the lipoxygenase is desirable (see at least page 727, column 2, the 1st full paragraph).

Kleinhofs et al teach barley mutants with single gene mutation and methods for generating said plants. Kleinhofs et al teach waxy endosperm mutants that occurred at high frequency in barley using sodium azide to induce the mutation. Because specific gene or function mutations occur with high frequency in azide-mutegenized barley, Kleinhofs et al suggest that the method can be used to produce barley mutants with a desired gene mutation/loss of function.

Therefore, it would have been obvious to one of ordinary skill in the art at the time this application was filed to use the method of inactivating lipoxygenase in barley as taught by Rutgersson, and to modify that method by incorporating the use of sodium azide to induce stable LOX-1 mutation/loss of function in barley to produce barley LOX-1 mutant with null or reduced LOX-1 function as suggested by Rutgersson with a reasonable expectation of success, given the high frequency single gene function/ mutations occurrence in azide-mutegenized barley as taught by Kleinhofs et al. One would have been motivated to produce barley plants having reduced Lox-activity, given that low or no lipoxygenase activity in barley improves oxidative stability of cereal product, and given that lipoxygenase is the main factor in off-flavor production in malt as taught by Rutgersson et al. the premature nonsense codon or splice site mutation in the LOX-1 is an inherent property of the LOX-1 mutant barley. Therefore, the invention as

whole was a prima facie obvious. Claims 8 and 11 are included in the rejection because "a progeny plant" does not necessarily comprise the deposited seed.

Applicant argues that the method described by Rutgersson is not useful for producing barley plants with a total loss of function of LOX-1 because it is non-specific and does not only target LOX-1 activity but applies to all lipoxygenases. This is not found persuasive because the rejected claims are drawn to barley plant or part thereof with null or less than 1% of LOX-1 function; embryos of said plant comprise less than 5% of the embryos of wild-type barley. According to the claims, the claimed barley can be produced by any method as long as plants with reduced LOX-function are produced. In addition, Applicant has not shown the unexpected agronomic quality of barley mutants with null LOX-1 function as compared the barley mutants with less than 5% LOX-1 activity of the wild-type LOX-1.

Furthermore, Rutgersson describes conditions which lipoxygenase inactivation was achieved in barley kernels. Table II shows remaining activity of lipoxygenase was 2% (for experiment 13). In addition, while the prior art method targets other enzymes and lipoxygenase, the cited reference clearly indicates that the targeted activity is LOX-1 since the plant materials used in the experiment are the barley kernels which contains LOX-1 (see Methods and Materials on page 727) as known to one of ordinary skill in the art. In addition, since the rejection is one of obviousness and not one of anticipation, neither Rutgersson et al nor Kleinhofs need to teach barley plant or part thereof with total loss LOX-1 activity.

Claim Rejections - 35 USC § 103

Claims 1-14 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douma et al (WO 02/053721) This rejection is repeated in part for the reasons of record as set forth in the last Office action of 10/24/06. Applicant's arguments filed 01/24/07 and 1/30/07 have been fully considered but are not deemed persuasive.

Applicant argues that Douma et al do not disclose an enabling disclosure for the production of barley plants having mutation that caused total loss of LOX-1 function. Applicant also argues that the instant application discloses new and efficient screening methods using embryos and kernels to identify mutants with null or little LOX-1 activity. Applicant further argues that antisense technology is insufficient to provide total inhibition of gene function. Applicant also argues that methods for preparing specific mutations using chimeric RNA/DNA for use in barley plants were not known at the time of filing the present application.

These are not found persuasive because the rejected claims are drawn to barley plants with total loss or reduced LOX-1 activity and not to methods screening mutants using embryos and kernels to identify mutants with null or little LOX-1 activity. Douma et al teach barley cultivars having greatly reduced lipoxygenase-1 activity (figure 16). The barley plants contain a mutant lox-1 gene expressing greatly reduced levels of the isoenzyme lipoxygenase-1 for the production of flavor-stable beverage.

Furthermore, Figure 13 of the Douma et al shows the lox-1 gene of cultivar Vintage (wild-type) and the mutant lox-1 gene of Line G. Two mutations in the lox-1 gene are indicated. Figure 16 shows sequence alignment between the wild-type and

mutant lox-1 gene is due to a point mutation at nucleotide 2347. Douma et al also teach that known genetic approaches chemical and radiation induced mutagenesis, and site-directed mutagenesis can be used to produce the plants with reduced level of lipoxygenase 1 in a barley plant in a stable and inheritable manner.

Regarding the chimeric DNA/RNA oligonucleotides to induce site directed mutagenesis, it is noted that Zhu et al (1999, Proc. Natl. Acad. Sci. 96: 8768-8773) cited in Douma et al have successfully shown to introduce mutations in plant cells at desired locations. Douma et al also teach that the chimeric RNA/DNA oligonucleotides can be transformed into the barley protoplasts or cells of interest using the PEG-mediated or particle bombardment-mediated transformation methods known in the art; the individual protoplasts or cells can then be regenerated by tissue culture to produce fertile plants; and the mutational event can be confirmed using a PCR-based approach as detailed in Therefore, Douma et al provide an enabling disclosure and sufficient guidance for how to produce barley mutants with severely reduced LOX-1 activity.

Double Patenting

Claims 1-14 and 48-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,660,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the issued patent are drawn to barley plants or parts thereof with null or greatly reduced LOX-1 activity as compared to a wildtype-barley plant, and methods for producing said plants and plant parts. This rejection is repeated in part for the reasons of record as set forth in

the last Office action of 10/24/06. Applicant's arguments filed 01/24/07 and 1/30/07 have been fully considered but are not deemed persuasive.

Applicant argues that the claims of US 6,660,915 are drawn to barley plants carrying a specific mutation in the LOX-1 gene identified by SEQ ID NO: 12, grains, barley plants with 10% Lox-1 activity, and products from said plants and methods of producing beer; while the claims of the instant application are directed to barley plants with a mutation in the LOX-1 gene causing a total loss of LOX-1 function.

These are not found persuasive because the instantly claimed barley plants define genus of barley plants that encompass the species of the barley plants with specific mutation in the LOX-1 gene identified by SEQ ID NO: 12 of the patent. MPEP 2131.02 states "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. See In re Slayter (276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960). In addition, claim 1 of the patent recites "the plant or portion characterized by a reduction or absence of LOX-1 activity as compared with a non-mutated control". Therefore, the rejection is proper.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/12/07
Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PRIMARY EXAMINER